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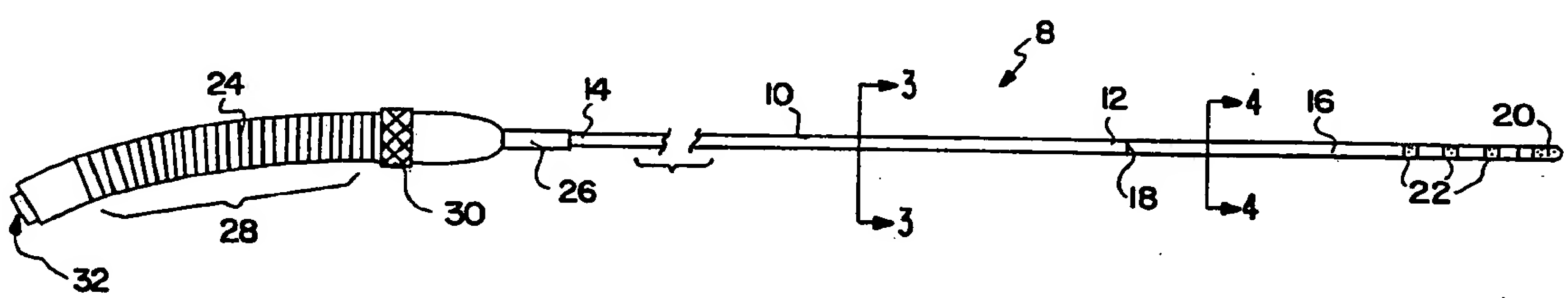

(57) Abstract

A steerable catheter (8) suitable for radiofrenquency ablation of cardiac tissue comprises a catheter shaft (15) with a deflectable tip (16) at the distal end of the shaft. The tip is deflected by means of a shapable handle (24) coupled to pull wires fastened to the distal end of the deflectable tip. A core wire (42) extends from the handle to the distal tip, providing fine positioning of the deflectable tip by applying torque through the core wire to the tip. A spring tube (58) is further provided in the deflectable tip for improved torque transmission and kink-resistance. The catheter has an electrode at the distal end of the deflectable tip for positioning at a target site and applying RF power to accomplish ablation.

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SHAPABLE HANDLE FOR STEERABLE ELECTRODE CATHETER

BACKGROUND OF THE INVENTION

The present invention relates generally to the field of electrophysiology. More particularly, this invention relates to methods and apparatus for treating cardiac arrhythmias.

Symptoms of abnormal heart rhythm are generally referred to as cardiac arrhythmias, with an abnormally slow rhythm being classified as a bradycardia and an abnormally rapid rhythm being referred to as a tachycardia. The present invention is concerned with the treatment of tachycardias which are frequently caused by the presence of an "arrhythmogenic site" or "accessory atrioventricular pathway" close to the inner surface of one of the chambers of the heart. The heart includes a number of normal pathways which are responsible for the propagation of signals necessary for normal electrical mechanical function. The presence of arrhythmogenic sites or accessory pathways can bypass or short circuit the normal pathways, potentially resulting in very rapid heart contractions, referred to as tachycardias. Tachycardias may be defined as ventricular tachycardias (VT's) and supraventricular tachycardias (SVT's). VT's originate in the left or right ventricle and are typically caused by arrhythmogenic sites associated with a prior myocardial infarction. SVT's originate in the atria and are typically caused by an accessory pathway.

Treatment of both ventricular and supraventricular tachycardias may be accomplished by a variety of approaches, including drugs, surgery, implantable pacemakers/defibrillators, and catheter ablation. While drugs may be the treatment of choice for many patients, they only mask the symptoms and do not cure the underlying cause. Implantable devices only correct the arrhythmia after it occurs. Surgical and catheter-based treatments, in contrast, will actually cure the problem, usually by ablating the

abnormal arrhythmogenic tissue or accessory pathway responsible for the tachycardia. The catheter-based treatments rely on the application of various destructive energy sources to the target tissue, including direct current electrical energy, radiofrequency electrical energy, laser energy, and the like.

Of particular interest to the present invention are radiofrequency (RF) ablation protocols which have proven to be highly effective in tachycardia treatment while exposing the patient to minimum side effects and risks. Radiofrequency catheter ablation is generally performed after an initial mapping procedure where the locations of the arrhythmogenic sites and accessory pathways are determined. After mapping, a catheter having a suitable electrode is introduced to the appropriate heart chamber and manipulated so that the electrode lies proximate the target tissue. Radiofrequency energy is then applied through the electrode to the cardiac tissue in order to ablate a region of the tissue which forms part of arrhythmogenic site or the accessory pathway. By successfully destroying that tissue, the abnormal signalling patterns responsible for the tachycardia cannot be sustained. A method and system for performing RF ablation by controlling temperature at the ablation site is described in co-pending application Serial No. 07/866,683, entitled "Method and System for Radiofrequency Ablation of Cardiac Tissue," Attorney Docket No. 14875-8, the full disclosure of which is hereby incorporated herein by reference.

Catheters utilized in radiofrequency ablation are inserted into a major vein or artery, usually in the neck or groin area, and guided into the chambers of the heart by appropriate manipulation through the vein or artery. The tip of the catheter must be manipulable by the user from the proximal end of the catheter, so that the distal electrode can be positioned against the tissue region to be ablated. The catheter must have a great deal of flexibility in order to

follow the pathway of the major blood vessels into the heart, and the catheter must permit user manipulation of the tip even when the catheter is in a curved and twisted configuration. Because of the high degree of precision required for proper positioning of the tip electrode, the catheter must be manipulable with a high degree of sensitivity and controllability. In addition, the distal portion of the catheter must be sufficiently resilient in order to be positioned against the wall of the ventricle and maintained in a position during ablation without being displaced by the movement of the beating heart. Along with the steerability, flexibility and resiliency, the catheter must have a sufficient degree of torsional stiffness to permit user manipulation from the proximal end.

Steerable catheters are known for use in various medical procedures. See, for example, U.S. Patent No. 4,998,916 to Hammerslag, U.S. Patent No. 4,944,727 to McCoy, U.S. Patent No. 4,838,859 to Strassmann, U.S. Patent No. 4,826,087 to Chinery, U.S. Patent No. 4,753,223 to Bremer, U.S. Patent No. 4,685,457 to Donenfeld, U.S. Patent No. 3,605,725 to Bentov, U.S. Patent No. 3,470,876 to Barchilon and U.S. Patent No. 4,960,134 to Webster, Jr. Typically, such catheters employ a plurality of steering wires, usually three or four, extending from a steering mechanism at the proximal end of the catheter to an anchor point at the distal end of the catheter. By tensioning certain of the steering wires using the control mechanism, the tip of the catheter can be manipulated in a desired direction. Known steering mechanisms include joy sticks, e.g. U.S. patent nos. 4,960,134, 4,944,727, 4,838,859, 4,826,087, and 3,605,725, movable plates, e.g. U.S. patent no. 4,998,916, and trigger arms, e.g. U.S. patent no. 3,470,876.

In addition to being steerable in the lateral direction, further positioning of known catheters is accomplished by rotating the catheter as a whole about its

longitudinal axis, typically by turning or twisting the proximal end of the catheter. This exerts a torque along the length of the catheter which is translated into a rotational motion at the distal end, allowing a laterally deflected distal tip to be rotated.

While radiofrequency ablation using existing catheters has had promising results, such catheters suffer from certain disadvantages. In particular, the steering mechanisms utilized in known catheters have proven to be awkward and ill-suited to the delicate and precise positioning required in ablation procedures. Joysticks and other known mechanisms frequently lack any obvious correspondence between the deflection of the mechanism and the resulting deflection produced at the distal tip of the catheter. Moreover, previous joysticks tend to be complex and are often costly and difficult to manufacture in volume. Further, known mechanisms usually have an additional actuator member as an appendage of the catheter handle, requiring the user to simultaneously maintain a grip on the catheter while actuating the steering mechanism, an action which frequently requires the use of more than one hand. In addition, joysticks and other manipulators are frequently unable to apply the amount of force required to manipulate a pull wire system, in catheters or other instruments.

For these and other reasons, a steerable catheter suitable for radiofrequency ablation is desired which is steerable from its proximal end in a controllable and convenient manner. The catheter should have a steering mechanism for high-precision positioning of then catheter's distal end which is simplified and intuitive in operation. Preferably, the direction and magnitude of deflection produced at the distal end of the catheter will correlate with the direction and magnitude of movement of the steering mechanism. It would be further desirable for the steering mechanism to be integrated into the handle of the catheter to facilitate

simultaneously holding and steering mechanism to be integrated into the handle of the catheter to facilitate simultaneously holding and steering the catheter with one hand. Such designs should also facilitate simultaneous tip deflection and rotation of the catheter (by applying torque to the proximal end). In addition, the steering mechanisms or "manipulators" should be able to apply relatively large manipulation forces and be adaptable to function with any type of instrument having a pull wire deflection system, such as endoscopes and industrial equipment.

SUMMARY OF THE INVENTION

The present invention provides an improved manipulator, in particular a shapable handle, for use with a steerable catheter in radiofrequency ablation, where the shapable handle is disposed at the proximal end of the catheter for steering the deflectable tip of the catheter. The shapable handle will be suitable for use with other equipment and instruments which rely on a pull wire system for tip deflection. In one embodiment, the shapable handle comprises a deformable body capable of being attached at its distal end to the proximal end of the catheter, with a proximal portion of the body attached to a linkage from the deflectable tip of the catheter, wherein deforming the body about a first transverse axis deflects the deflectable tip about a second parallel or non-parallel transverse axis. Preferably, the deformable body comprises convoluted tubing, and is substantially non-resilient so as to retain its shape after being deflected. Usually, the linkage from the deflectable tip comprises at least one pair of pull wires, the distal ends of the pull wires being coupled to radially offset locations at the distal end of the deflectable tip, and the proximal ends of the pull wires being attached to radially offset locations at the proximal end of the deformable body, whereby deforming the body about the first transverse axis tensions at least a first of the pull wires. The pull wires

are preferably disposed in radially offset lumens extending from the distal end to the proximal end of the body.

In a further embodiment, the shapable handle includes means for torquing the deflectable tip about a longitudinal axis of the catheter shaft without rotating the handle of the catheter. Usually, the means for torquing comprises a core wire extending from the deflectable tip to the handle, and means mounted on the handle for applying torque to a proximal end of the core wire, whereby the torque applied is transmitted to the distal end of the deflectable tip.

In addition, the handle preferably includes a connector to which lead wires from the electrodes at the distal end of the catheter are coupled. The connector will typically be capable of being connected to an RF power supply, as well as to mapping or diagnostic equipment.

The steerable catheter of the present invention has several important advantages over known catheters. The catheter of the invention is steerable from its proximal end with sensitivity and precision. The shapable handle provides a steering mechanism which is much simplified in operation over existing mechanisms. The shapable handle provides an obvious and logical correlation between the motion of the handle and the resulting deflection produced in the tip of the catheter. The shapable handle further provides means for holding, steering and rotating the catheter in a single member, conveniently operable using a single hand, eliminating the awkwardness of a separate actuator extending from the catheter handle.

The invention and objects and features thereof will be more readily apparent from the following detailed description and appended claims when taken with the drawings.

BRIEF DESCRIPTION OF THE DRAWING

Fig. 1 is a front elevational view of the steerable catheter constructed in accordance with the principles of the present invention.

Fig. 2 is a front elevational view of the distal portion of the catheter of Fig. 1.

Fig. 3 is a cross-sectional view of the catheter body taken along line 3-3 of Fig. 1.

Fig. 4 is a cross-sectional view of the distal portion of the catheter taken along line 4-4 of Fig. 1.

Fig. 5 is a front cross-sectional view of the distal tip of the catheter of Fig. 1.

Fig. 6 is a front elevational view of the core wire of the catheter of Fig. 1.

Fig. 7 is a front elevational view of a pull wire of the catheter of Fig. 1.

Fig. 8 is a front view of the anchor plate of the catheter of Fig. 1.

Fig. 9 is a side cross-sectional view of the shapable handle of the catheter of Fig. 1.

Fig. 10 is a schematic of the shapable handle of the catheter of Fig. 1.

Fig. 11 is a schematic of the catheter of Fig. 1 positioned in the heart of a patient according to the principles of the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

Referring to Fig. 1, a steerable catheter 8 constructed in accordance with the principles of the present invention comprises a shaft 10 having a distal end 12 and proximal end 14. A tip section 16 is fused at butt joint 18 to distal end 12 of shaft 10. A tip electrode 20 is mounted at the distal end of tip section 16, with band electrodes 22 disposed on tip section 16 proximally of tip electrode 20. A thermocouple (not shown) is located in the distal end of the

tip section 16 and in thermal contact with the tip electrode 20. Proximal end 14 of shaft 10 is mounted to handle 24 through strain relief 26. Handle 24 includes a shapable body 28 in a middle portion thereof. A torque ring 30 is disposed about handle 24 distally of shapable body 28, as shown in Fig. 1, or proximally thereof. At the proximal end of handle 24 is electrical connector 32 for connecting tip electrode 20, band electrodes 22 and the thermocouple to RF power, mapping, and/or temperature measuring equipment. Tip section 16, as illustrated in Fig. 2, is flexible and laterally deflectable into various configurations using shapable handle 24. Preferably, tip section 16 can be deflected by at least 270° from the straight, distally-pointing configuration of Fig. 1 (as illustrated in Fig. 2).

Referring now to Figs. 1, 3 and 5, shaft 10 comprises an outer jacket 34, which may be nylon, urethane or other plastic. Outer jacket 34 surrounds stiffener 36, which usually comprises a stainless steel braid or coil. The stiffener 36 is disposed about a base layer 38, which preferably comprises a tube of polyimide or other relatively stiff, high durometer material. The stiffness and torqueability characteristics of the shaft can be varied by varying the type of material used for outer jacket 34, stiffener 36 and base layer 38, as well as by using different geometries for the stiffener 38. For example, the stiffener 36 could be a braid or a coil, where the number of filaments, shape of filaments, coiling or weaving pattern, number of turns, and the like, can be varied individually or in combination to provide a desired stiffness. Preferably, the polyimide tube of base layer 38 has a thickness in the range from 0.002 in to 0.005 in.

Outer jacket 34, stiffener 36 and base layer 38 define a central lumen 40 extending the length of shaft 10. Disposed in central lumen 40 are a core wire 42, pull wires 44, electrode wires 46 and thermocouple wires 48.

Referring now to Figs. 1, 4 and 5, tip section 16 comprises tubing 50 of a low durometer flexible plastic, such as Pebax™, silicone rubber, or other resilient material. Preferably, tip section 16 has a durometer in the range of 30A to 60D. Tubing 50 usually has at least four lumens 44 extending its length in parallel to its longitudinal axis, a central lumen 54 and at least three radially offset lumens 56 (with four being illustrated). Core wire 42 extends through central lumen 54, along with electrode wires 46 and thermocouple wires 48. Pull wires 44 (not shown in Figs. 3 and 4) extend from the central lumen of shaft 10 to the radially offset lumens 56 of tip section 16.

A spring tube 58 is also disposed in central lumen 54 of tip section 16, the spring tube 58 fitting snugly against the walls of inner lumen 54 and having a hollow center through which core wire 42, electrode wires 46 and thermocouple wires 48 extend. Spring tube 58 usually comprises a polyimide tube which provides lateral and torsional stiffness as well as kink-resistance to tip section 16. The spring tube 58 could also be a braided or coiled structure, or a composite of multiple layers.

Referring now particularly to Fig. 5, tip section 16 is fixed to shaft 10 at butt joint 18, preferably by heat welding. Central lumen 54 of tip segment 16 is of smaller diameter than central lumen 40 of shaft 10, with spring tube 58 extending a distance, typically about 0.5 in., into the central lumen 40 of shaft 10. Such extension serves to limit kinking at or near butt joint 18 when tip section 16 is deflected. A proximal end 60 of the spring tube 58 will extend into central lumen 40, thereby enhancing the stiffness at the transition between the tip section 16 and the remainder of the shaft 10.

Core wire 42, electrode wires 46 and thermocouple wires 48 extend from central lumen 40 of shaft 10 into central lumen 54 of tip section 16 through the center of spring tube

58. At the distal end of tip section 16, spring tube 58 emerges from central lumen 54 into an aperture 64 within tip electrode 20. RF power wire 66 (one of electrode wires 46) is coupled to tip electrode 20. Thermocouple wires 48 terminate in a thermocouple 68 disposed within aperture 64. Preferably, aperture 64 is filled with high temperature adhesive to maintain thermocouple 68 in position. Electrode band wires 70 exit central lumen 54 within spring tube 58 and couple to band electrodes 22. Core wire 42 extends through central lumen 54 into aperture 64 of tip electrode 20.

An electrically and thermally insulating anchor plate 72 is bonded to distal end 74 of tubing 50, tip electrode 20 being bonded to the distal side of anchor plate 72. Anchor plate 72, as shown in Fig. 8, has a central passage 78 corresponding to central lumen 54 of tip section 16, and four radially offset apertures 76 through which pull wires 44 pass. Referring again to Fig. 5, pull wires 44 terminate in anchors 80, which usually comprise steel balls formed on or welded to ends of pull wires 44. The anchors 80 are of larger diameter than apertures 76, providing a strong, pivotal connection between pull wires 44 and the distal end of tip section 16. Anchor plate 72 serves several functions. First, it protects the catheter body from thermal damage during ablation, allowing for many RF applications without catheter degradation. Secondly, it provides a strong component to which the pull wires 44 can be attached, without reliance on adhesive. Third, anchor plate 72 provides a means of electrically insulating the pull wires 44 from tip electrode 20, preventing the RF current from traveling back up the catheter to the handle assembly. The anchor plate may be formed from any polymeric or ceramic material having the necessary mechanical strength and electrical and thermal insulating properties. Preferred is the use of polyether ether ketone, available from ICI Americas, Inc., Wilmington, Delaware, under the tradename Victrex.

Referring now to Fig. 6, core wire 42 is usually stainless steel, and is tapered, typically being ground in three sections of different diameter separated by tapered transition sections 82. Proximal shaft portion 84 has the largest diameter, to provide the greatest stiffness both laterally and torsionally to the proximal portion of shaft 10 of the catheter. Distal shaft section 86 has an intermediate diameter, providing significantly more flexibility than that of the proximal shaft section 84 so as to allow deflection of the corresponding distal portion of shaft 10 of the catheter. Distal portion 88 of core wire 42 is of the smallest diameter, lending the highest degree of flexibility to tip section 16. The graduated diameters of the core wire permit deflection of tip section 16 at a constant or near constant radius. Core wire 42 further provides a structural member continuous from the proximal end to the distal end of the catheter having a significant degree of torsional stiffness. The taper profile of the core wire 42 may of course be varied to obtain any of a variety of tip shapes.

In addition to controlled flexibility, the core wire can provide an alternate means for transmitting torque to the catheter tip. By coupling the core wire to a rotatable ring on the handle of the catheter, as described below, torque can be applied to the distal tip of the catheter without having to rotate the entire handle assembly. The core wire further permits greater controllability and sensitivity in rotational positioning of tip electrode 20 than is afforded by turning the entire handle and catheter assembly.

Usually, pull wires 44 are stainless steel coated with a low friction plastic such as polytetrafluoroethylene (available from DuPont under the tradename Teflon®). Electrode wires 46 are usually nickel for increased tensile strength but could be copper or other electrically conductive metals. Thermocouple wires 48 are usually copper and constantan, respectively. Referring now to Fig. 9,

the shapable handle 24 of the steerable catheter 8 will now be described. Shaft 10 is mounted to the distal end 90 of handle 24 through strain relief 26. Outer jacket 34 of shaft 10 is fixed to handle 24 by heat or adhesive bonding, or other known means. Handle 24 is comprised of a nose cover 92, a distal frame member 94 adjacent nose cover 92, a torquer ring 96 disposed about a portion of distal frame member 94, a core wire retainer 100 disposed beneath the torquer ring 96 and received in a cavity 101 formed in the distal frame member 94, and convoluted tubing 104 extending between the distal frame member 94 and a proximal frame member 106. The convoluted tubing 104 may alternately be formed as a series of stacked disks, a gooseneck structure, or the like. The electrical connector 32 is secured to proximal end of proximal frame member 106. In addition, a bridge member 110, usually a nylon or polyethylene tube, extends between proximal frame member 106 and the distal frame 94 and is bonded at each end by adhesives or other means. Electrode wires 46 and thermocouple wires 48 extend from the connector 36 in proximal frame member 106 through bridge 110 to nose cover 92 and into shaft 10. A spring 113 is also disposed through the central bore 112 in order to enhance the hoop strength of the convoluted tube 104.

Core wire 42 enters nose cover 92 from shaft 10 and angles radially outward so as to mechanically couple with torquer ring 96. The proximal end of core wire 42 is fixed to core wire retainer 100, usually by extending through a center hole through core wire retainer 100 and being engaged by an adhesive or a set screw (not illustrated) extending radially inward. Core wire retainer 100 is cylindrical in shape and lies within a cavity 101 of torquer ring 96, such that turning torquer ring 96 rolls core wire retainer 100. Usually, the outer surface of core wire retainer 100 is knurled, and a friction pad 120 is disposed between core wire retainer and torquer ring 96, for improved contact therebetween. Other mechanisms for applying torque to the proximal end of the core

wire 42, of course, would also be available, such as rack and pinion systems where the interior surface of torquer ring 96 would have a gear surface to engage an exterior gear surface of retainer 100. It would also be possible for the retainer 100 to have a cross-sectional shape other than round, such as oval, in order to transmit a variable force to the core wire 42. Thus, by rotating torquer ring 96, core wire retainer 100 is rotated, thereby applying a torque to the proximal end of core wire 42, where the torque will be transmitted to the distal tip section 16 of the catheter 8.

The relative diameters of the core wire retainer 100 and torque ring 96 will be selected to provide a particular ratio between ring rotation and wire rotation, usually being 1:4 (torquer ring:control wire). In this way, a small rotation of the torque ring 96 can cause a greater rotation of the proximal end of core wire 100. The ratio can be varied depending, for example, on the torsional stiffness of the core wire 100 and other variable factors.

Pull wires 44 enter the handle from shaft 10 and angle radially outward so as to pass through tubes 122. Tubes 122 are usually composed of stainless steel and extend through the distal frame member 94, the passages 126 in convoluted tube member 104 and to anchor points 124 at the proximal end of proximal frame member 106. Preferably, anchor points 124 comprise tensioning screws for adjusting the tension of pull wires 44. To provide controlled friction at the distal end of tubes 122 on the pull wires 44, sleeves 123 are received in holes in the distal face of distal frame member 94. Set screws 125 hold the sleeves 123 in place and can be used to increase friction by tightening. In this way, friction on the pull wires 44 can be adjusted to permit axial motion of the wires while the handle is being shaped, while holding the wires in place when the handle is not being shaped.

Referring now to Fig. 10, convoluted tubing 104 is preferably nylon or other flexible material, and is configured

to have alternating cylindrical segments of larger and smaller diameter such that the tubing is longitudinally expandable and contractible. This permits the convoluted tubing member 104 to be deflected laterally with respect to a distal portion. By such deflection, a lateral portion 134 of tubing member 104 at the outside of the bend becomes elongated, while the opposing lateral portion 136 at the inside of the bend is shortened. In this manner, pull wires 44 in tubes 122 are subject to tension or relaxation, depending upon in which lateral portion of tubing member 104 they are disposed, as shown by arrows 138.

Materials and dimensions of the convoluted tubing member or otherwise shapable member are selected so as to provide sufficient flexibility for deflection, and to be "deformable," i.e. to be substantially non-resilient so as to remain in a deflected position when force is released from the handle. Convoluted tubing 104 may alternatively comprise a plurality of alternating disks of larger and smaller diameter on a bendable core of a soft, malleable material such as copper or brass.

With this construction, as shown in Fig. 10, lateral deflection of a proximal portion of handle 24 by bending convoluted tubing member 104 exerts a tensile force to the pull wires 44 at the outside portion 134 of the bend, while relaxing tension to pull wires at the inside portion 136 of the bend. Accordingly, at the distal end of the catheter, pull wires 44 brought into tension pull the distal end via anchor plate 72, with the opposing relaxed pull wires allowing the tube to deflect. The attachment of pull wires 44 to handle 24 may be configured so that a particular deflection of handle 24 produces deflection of distal tip of the catheter in a desired direction, either corresponding to or complementary to the direction of deflection of handle 24.

Using the handle and catheter of the present invention, an electrode 20 is positioned within a chamber of

the heart using the catheter shown in Figs. 1-9. As illustrated in Fig. 11, the electrode 20, disposed at the distal end of the catheter 8 as described above, is percutaneously introduced through a major vein or artery, such as the aorta, to the heart chamber 140. Electrode 20 may then be positioned near the target site on the interior wall of the heart chamber for ablation. This is accomplished by deflecting shapable handle 24 so as to produce a corresponding deflection in distal tip section 16. Further rough positioning can be achieved by rotating or twisting handle 24 such that the entire catheter assembly rotates, translating the rotational motion to tip section 16. Fine positioning is then accomplished by rotating torquer ring 30 on handle 24, which turns core wore 42, applying a torque to tip section 16. This provides precise and controllable rotational positioning of tip electrode 20 at the target site. Ablation may then be performed by applying RF energy to the target location through electrode 20, which is coupled to connector 32 via wires 46, connector 32 being connected to an RF power supply.

While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those skilled in the art without departing from the true spirit and scope of the invention as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A steerable catheter comprising:

a catheter shaft having a distal end, a proximal end, and a central lumen extending therebetween, wherein a distal portion of the shaft is deflectable;

means in the central lumen extending from the proximal end to the distal end for deflecting the distal portion of the shaft about a transverse axis; and

a shapable structure attached to the proximal end of the catheter shaft and connected to the deflecting means such that producing a shape in the structure produces a corresponding shape in the deflectable portion of the shaft.

2. A steerable catheter as in claim 1 wherein the means for deflecting comprises at least one pair of pull wires coupled to radially offset locations at the distal end of the deflectable portion of the shaft and wherein the shapable structure is connected to selectively apply tension to the pull wires to deflect the deflectable portion of the shaft.

3. A steerable catheter as in claim 2 wherein the shapeable handle comprises a body having a deformable structure such that deflecting a portion of the body about a transverse axis lengthens at least a first laterally offset longitudinal portion of the body and shortens at least a second laterally offset longitudinal portion of the body.

4. A steerable catheter as in claim 3 wherein the shapable handle further comprises longitudinal guideways through the first and second laterally offset longitudinal portions of the body, each of the pull wires extending through one of the guideways, and a reinforcement spring within the deformable structure.

5. A steerable catheter as in claim 2 further comprising means for torquing the deflectable portion of the shaft about a longitudinal axis without rotating the handle.

6. A steerable catheter as in claim 5 wherein the means for torquing comprises a core wire extending from the deflectable portion of the shaft to the handle, and means mounted on the handle for applying torque to a proximal end of the core wire, whereby said torque is transmitted to the distal end of the deflectable portion of the shaft.

7. A steerable catheter comprising:

a catheter shaft having a distal end, a proximal end, and a central lumen extending therebetween;

a deflectable tip having a distal end, a proximal end, and a central lumen extending therebetween, wherein the proximal end of the distal tip extends from the distal end of the catheter shaft;

a shapable handle at the proximal end of the catheter shaft, at least a portion of the handle being deflectable about a transverse axis; and

a linkage coupled between the deflectable tip and the shapable handle, whereby deflecting the handle produces a corresponding deflection in the deflectable tip.

8. A steerable catheter as in claim 7 wherein the linkage comprises at least two pull wires coupled to radially offset locations at the distal end of the deflectable tip, the pull wires being connected to radially offset locations in a proximal end of the shapable handle to selectively apply tension to said pull wires to deflect the deflectable tip.

9. A steerable catheter as in claim 8 wherein the handle comprises a deformable body, wherein deflection of a portion of the body about a lateral axis lengthens at least a first laterally offset longitudinal portion of the body and shortens at least a second laterally offset longitudinal portion of the body.

10. A steerable catheter as in claim 8 wherein the body further comprises radially offset longitudinal guideways in said first and second laterally offset portions, each of

the pull wires extending through one of the guideways, and a reinforcement spring within the deformable structure.

11. A steerable catheter as in claim 8, further comprising means for torquing the deflectable tip about a longitudinal axis of the shaft without rotating the handle.

12. A steerable catheter as in claim 11 wherein the means for torquing comprises a core wire extending from the deflectable tip through the central lumen of the shaft to the handle, and means mounted on the handle for applying torque to a proximal end of the core wire whereby said torque is transmitted to the distal end of the deflectable tip.

13. A shapable handle for use with a steerable catheter, the catheter having a deflectable tip at its distal end with a linkage extending proximally therefrom, the handle comprising a deformable body capable of being attached at its distal end to the proximal end of the catheter, the linkage from the deflectable tip being coupled to a proximal portion of the body, wherein deforming the body about a first transverse axis deflects the deflectable tip about a second transverse axis.

14. A shapable handle as in claim 13 wherein the linkage comprises at least one pair of pull wires, and wherein the distal ends of the pull wires are coupled to radially offset locations at the distal end of the deflectable tip of the catheter and the proximal ends of the pull wires are attached to radially offset locations at the proximal end of the deformable body, whereby deforming the body about the first transverse axis tensions at least a first of the pull wires and relaxes at least a second of the pull wires.

15. A shapable handle as in claim 14 wherein the pull wires are guided along at least first and second guideways between the distal and proximal ends of the body, wherein deforming the body about the first transverse axis lengthens at least a first of the guideways and shortens at least a second of the guideways.

16. A shapable handle as in claim 15 wherein the body comprises a longitudinally expandable and contractable structure, wherein deforming the body about the first transverse axis lengthens a first lateral portion of the body and shortens an opposing second lateral portion of the body.

17. A shapable handle as in claim 16 wherein the expandable and contractable structure comprises convoluted tubing reinforced by an internal spring.

18. A shapable handle as in claim 17 wherein the guideways comprise radially offset lumens in the convoluted tubing extending from the distal end to the proximal end of the body, the pull wires extending through the lumens.

19. A shapable handle as in claim 13 further comprising means for torquing the deflectable tip about a longitudinal axis of the shaft without rotating the handle of the catheter.

20. A shapable handle as in claim 19 wherein the means for torquing comprises a core wire extending from the deflectable tip to the handle, and means mounted on the handle for applying torque to a proximal end of the core wire whereby said torque is transmitted to the distal end of the deflectable tip.

21. A shapable handle as in claim 19 wherein the catheter has at least a first electrode on the deflectable tip with lead wires extending therefrom, the handle further comprising a connector coupled to the lead wires for connecting to a radiofrequency power supply.

22. A steerable catheter comprising:

a catheter shaft having a distal end, a proximal end, and a central lumen extending therebetween;

a deflectable tip having a distal end, a proximal end, and a central lumen extending therebetween, wherein the proximal end of the distal tip is secured to the distal end of the catheter shaft;

a shapable handle secured to the proximal end of the catheter shaft, the handle having a deformable structure with at least two radially offset longitudinal lumens extending therethrough, at least a first of the lumens being lengthened and at least a second of the lumens being shortened when the handle is deformed about a transverse axis;

at least one pair of pull wires coupled to radially offset locations at the distal end of the deflectable tip extending proximally therefrom through the central lumen of the shaft and the lumens of the handle and attached to a proximal portion of the handle; and

means in the handle for torquing the deflectable tip of the catheter without rotating the handle.

23. The steerable catheter of claim 22 further comprising at least a first electrode disposed at the distal end of the deflectable tip; lead wires coupled to the electrode and extending to the handle; and a connector disposed in the handle and coupled to the lead wires for connecting to a radiofrequency power supply.

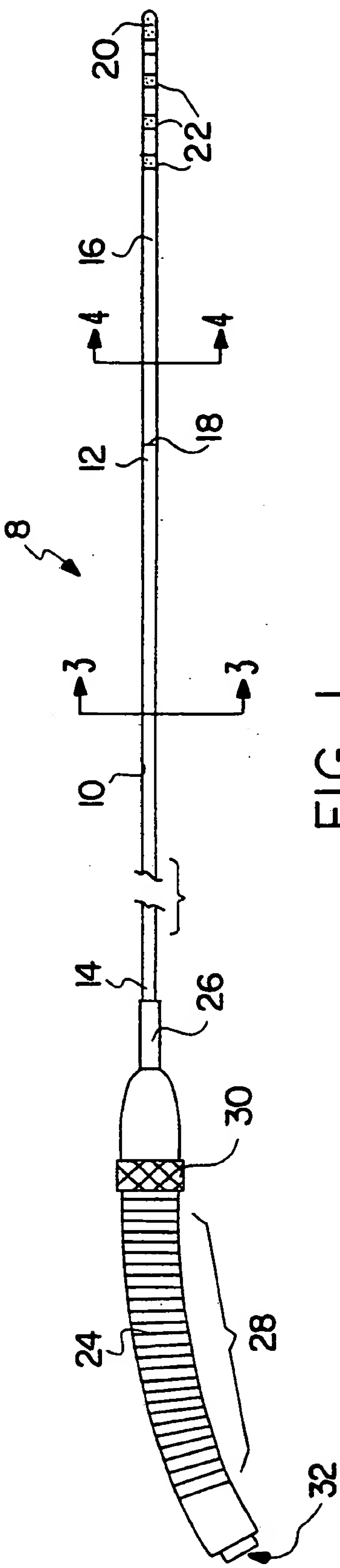

FIG. 1

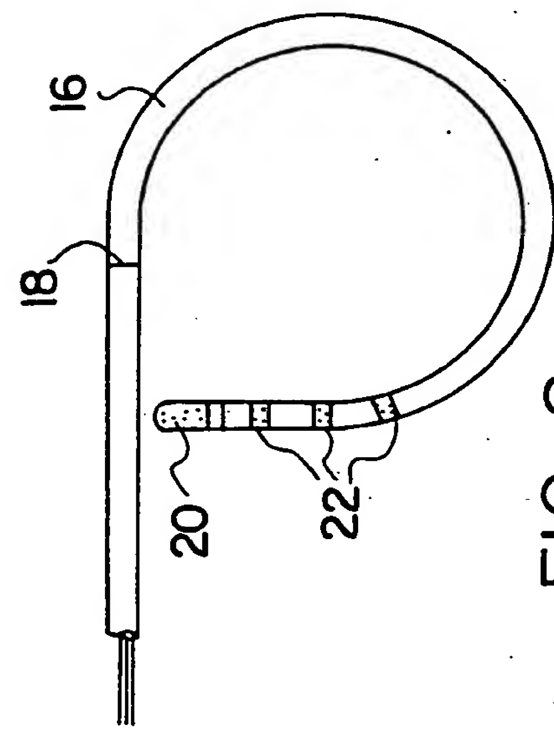

FIG. 2

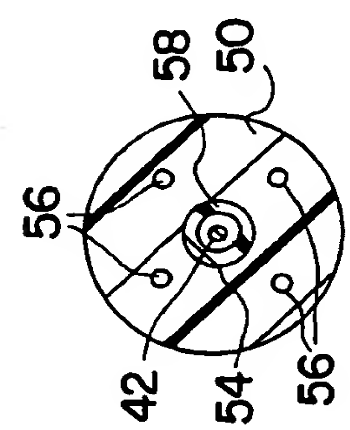

FIG. 4

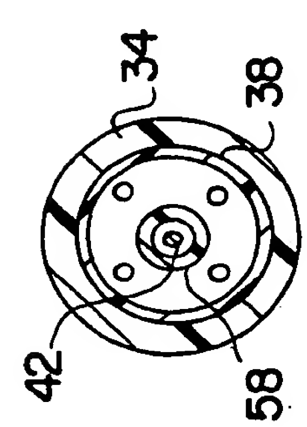

FIG. 3

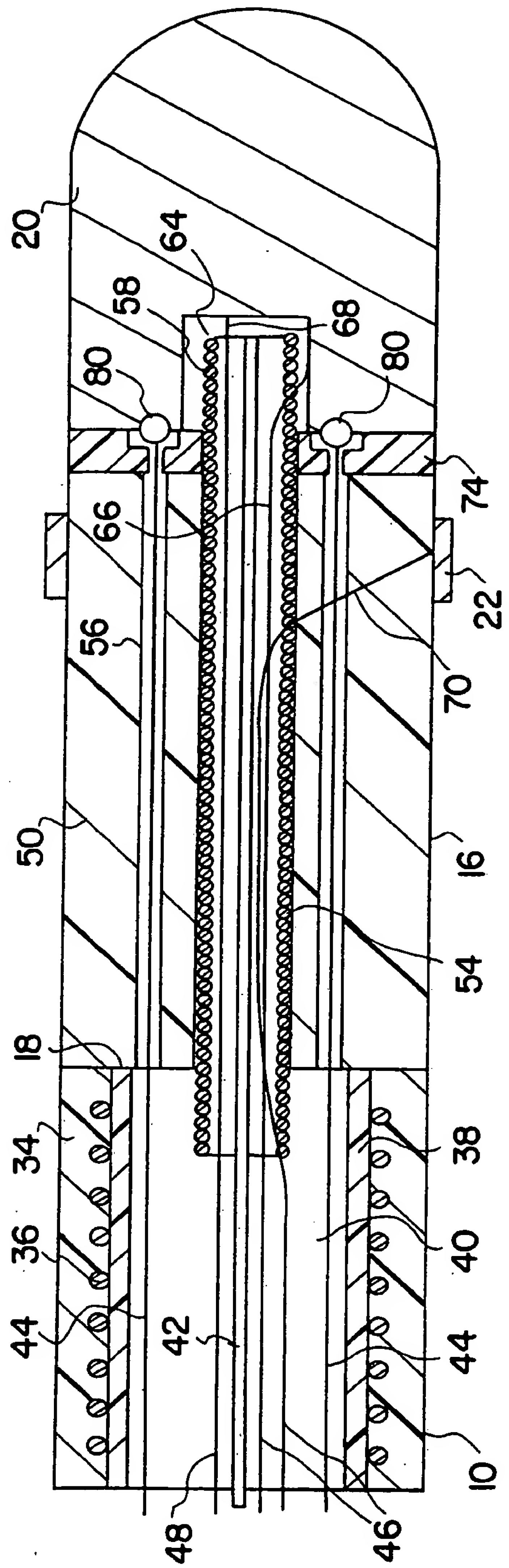
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FIG. 5

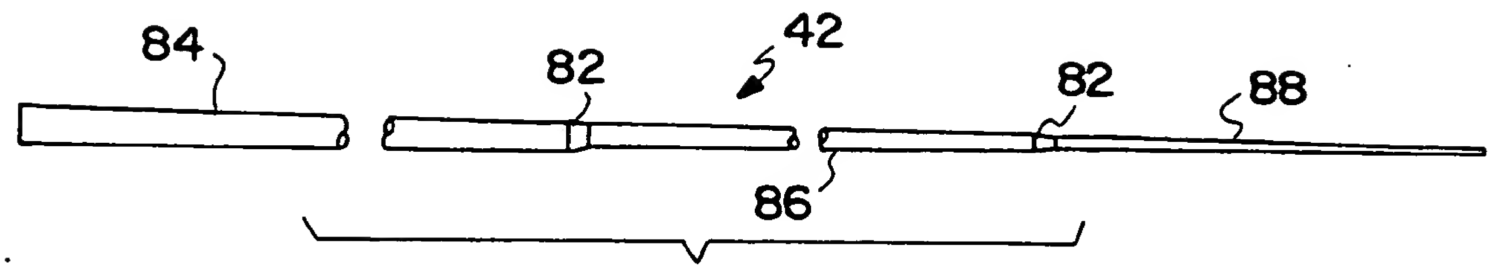

FIG. 6

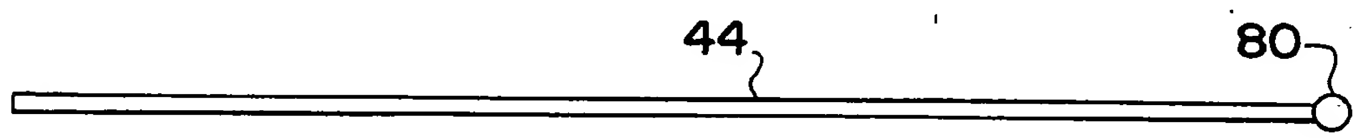

FIG. 7

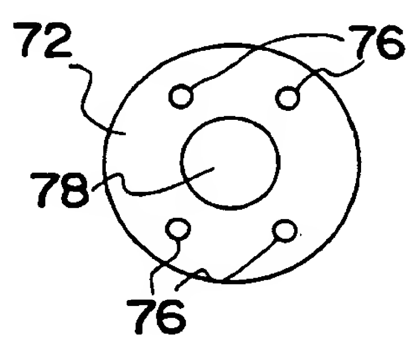

FIG. 8

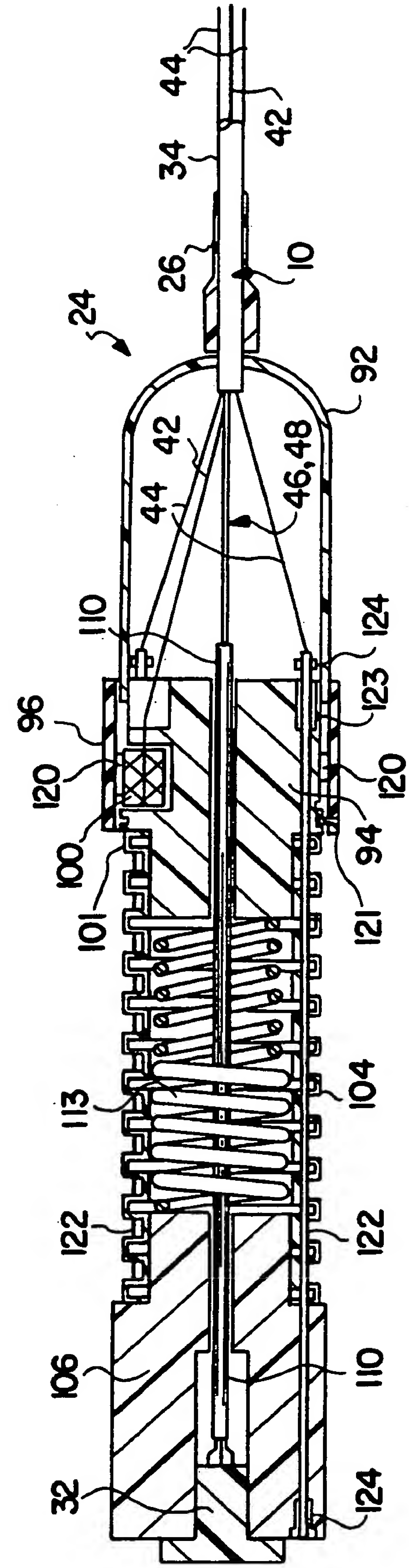
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FIG. 9

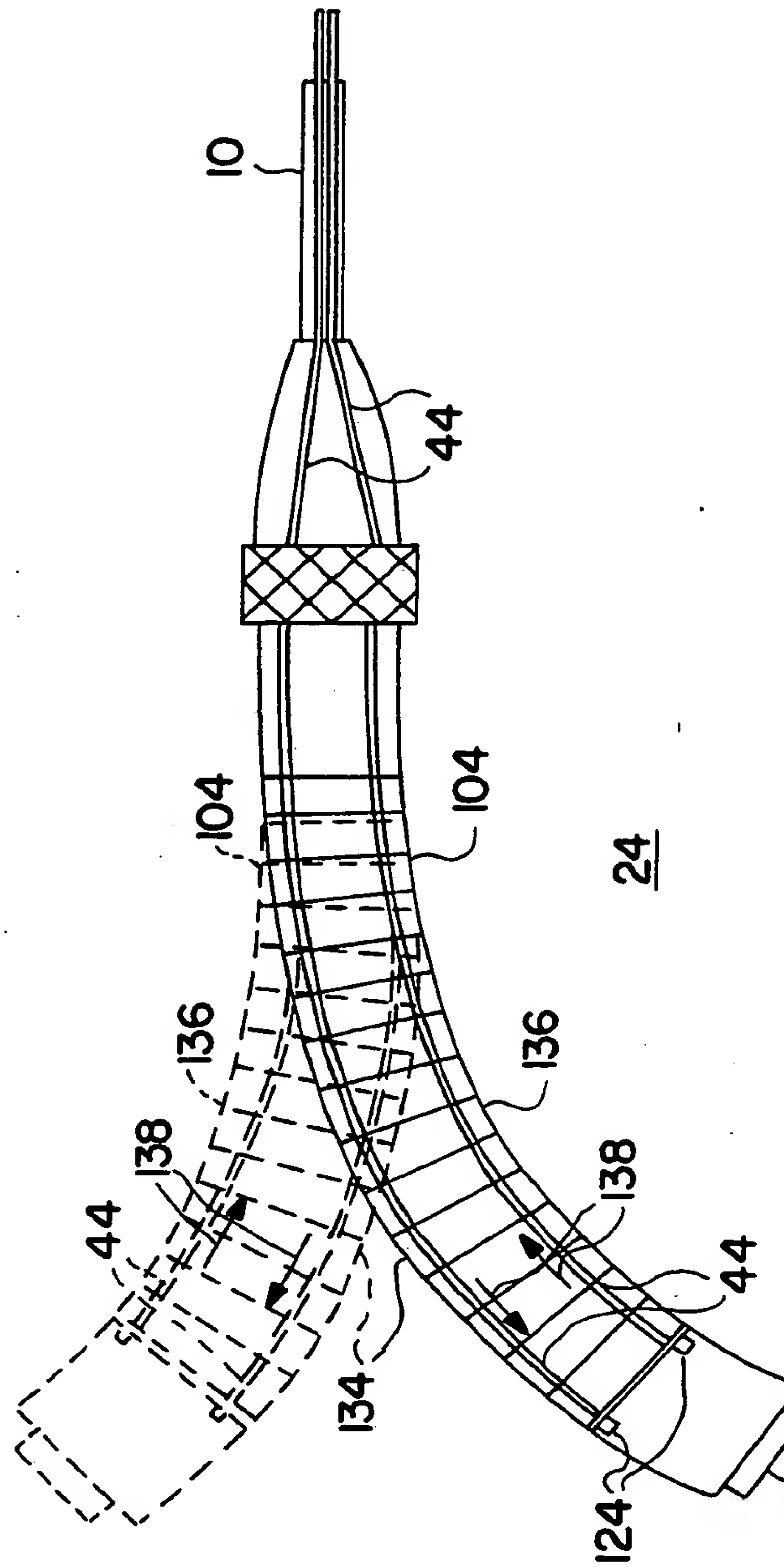

FIG. 10

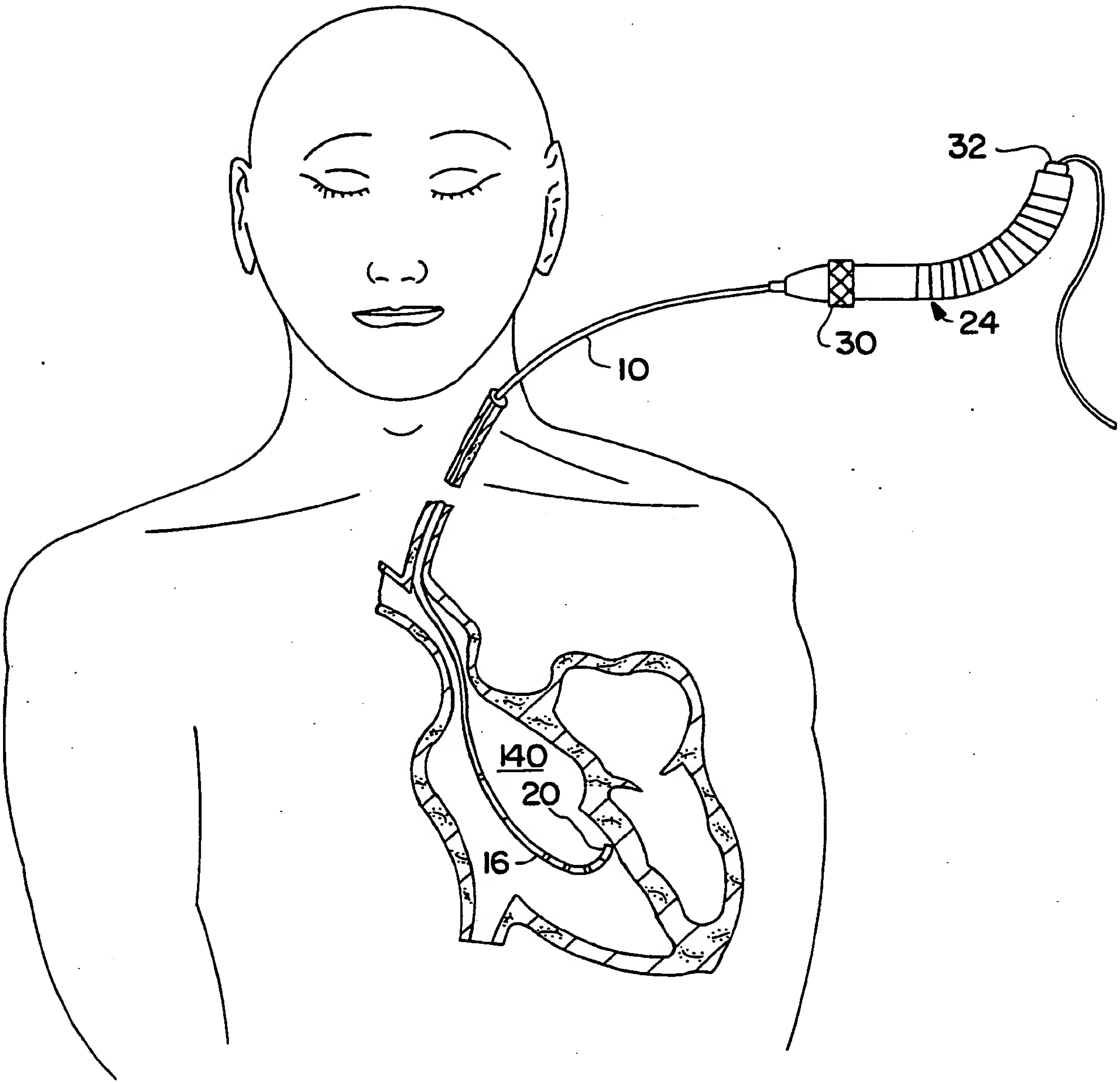

FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 93/03286

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M25/01

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M ; A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category°	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	WO,A,9 111 213 (EP TECHNOLOGIES, INC.) 8 August 1991 see page 19, line 22 - page 20, line 33; figures 14-15	1-23
A	US,A,3 547 103 (COOK) 15 December 1970 see column 2, line 52 - column 3, line 13; figure 6	1-23
A	US,A,3 470 876 (BARCHILLON) 7 October 1969 cited in the application see figures 1-4	1-23

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
28 JULY 1993	13.08.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9303286
SA 73284

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9111213	08-08-91	AU-A- 7304491	21-08-91
		EP-A- 0513224	19-11-92
		US-A- 5195968	23-03-93
US-A-3547103	15-12-70	None	
US-A-3470876	07-10-69	None	

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82